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DATE MAILED: 06/10/2005

APPLICATION NO. FILING DATE		DATE	. FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/646,545 08/21/2003		/2003	Douglas S. Hine	P-11138.00	9714		
7	590	06/10/2005	•	EXA	MINER		
Elisabeth L. Belden			RECEIVED	ALTER,	ALTER, ALYSSA M		
Medronic, Inc. 7000 Central A			OIPE/IAP	ART UNIT	PAPER NUMBER		
Mailstop B408		JUN 1 6 2005	2005 3762				
Minneapolis, MN 55432			2 4 2 3 3				

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	10/646,545	HINE ET AL.
Office Action Summary	Examiner	Art Unit
	Alyssa M. Alter	3762
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a rep If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be tim bly within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	rely filed s will be considered timely. the mailing of section (1997)
Status		
1) Responsive to communication(s) filed on 21 A	August 2003.	
	s action is non-final.	
3) Since this application is in condition for allows		
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.
Disposition of Claims		•
4)⊠ Claim(s) <u>1-12</u> is/are pending in the application		
4a) Of the above claim(s) is/are withdra	awn from consideration.	
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-12</u> is/are rejected. 7)□ Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/o	or election requirement	
	·	•
Application Papers		
9) The specification is objected to by the Examination 10) The drawing(s) filed on 21 August 2003 in terms		
10)⊠ The drawing(s) filed on <u>21 August 2003</u> is/are: Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the correct		
11)☐ The oath or declaration is objected to by the E		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority application from the International Burea	ts have been received. ts have been received in Applicationity documents have been receivent (PCT Rule 17.2(a)).	on No ed in this National Stage
* See the attached detailed Office action for a list	t of the certified copies not receive	d.
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 	Paper No(s)/Mail Da	te
Paper No(s)/Mail Date <u>4/15/04 & 2/02/05</u>	6) Other:	atent Application (PTO-152)

Art Unit: 3762

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation "of the array of lead contact elements" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-4, 6-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses a pacemaker with a connector bore for electrically and mechanically connecting the implantable medical device (IMD) with two adaptors and multi-electrode leads as displayed in figures 6 and 7. The array of lead connector elements are displayed in figure 2 as "sleeves 151 and 152 (in contact with rings 141 and 142) (col. 7, lines 63-64)". The sleeves are connected to electrodes, with a conductor for each electrode. The two adaptors, which the examiner considers the to be a plurality of adaptors, have an inner

Art Unit: 3762

lumen for engaging the sleeves of the lead with rings to create an electrical and mechanical connection. In addition, the adaptors have an external surface used for engagement with the electrical bore. This engagement surface has two contact zones, the pin as the first zone and sleeves of the lead as the second zone, which connects within the IMD with the socket and rings, respectively.

Since the lead connectors are located circumferentially around the lead, the examiner considers the connectors to be connector rings. In addition, a connector ring is located adjacent to the sealing ring and distal to the remainder of the array of lead connectors. Therefore, since the ring conductor makes contact with the bore of the IMD by means of the adaptor, the connector ring is located distal to the array of lead connector elements and electrically connected to the IMD bore.

Within the adaptor-lead connector, there are two sealing rings. One sealing ring, as previously mentioned, is located distal to the array of connector elements located on the lead. The other sealing ring is located on the adaptor located proximal to the array of connector elements.

Outer surface of a male connector piece closely matched the inner surface of a female connector piece the connection assembly is dimensioned to be press fit.

Therefore, since the sleeves or array of lead connector elements on the cylindrical male piece closely match the rings or contact elements located within the adaptor on a cylindrical female piece, the connection assembly is press fit.

Art Unit: 3762

Although, Pohndorf et al. is silent about the adaptors conforming to industry standard, it is inherent that the adaptors do conform to an industry standard in order for them to adequately perform with an IMD.

As to claims 1, 3 and 7, It has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 5 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934) in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the protrusions for each contact element within the array of lead contact elements. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to mechanically and electrically engage the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Pohndorf et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such

Art Unit: 3762

Page 5

a modification would be a substitution of f known functional equivalents by substituting electrical connectors to electrically engage the lead.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Bischoff et al. (US 5,843,141) discloses a medical lead connector system.

Art Unit: 3762

Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myssa M Alter
Examiner
Art Unit 3762

PHOARY EXAMINER

5/31/05

ELECTRONIC INFORMATION DISCLOSURE STATEMENT

Electronic Version v18

Stylesheet Version v18.0

Title of Invention

Multi-Polar Electrical Medical Lead Connector System

Application Number:

10/646545

Confirmation Number:

9714

First Named Applicant:

Douglas Hine

Attorney Docket Number:

P-11138.00

Art Unit:

3731

Examiner:

Search string:

(5341812 or 20030073348 or 20030050549).pn

US Patent Documents

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
M	_ 1	5341812	1994-08-30	Allaire et al.	Α	128	696

US Published Applications

Note: Applicant is not required to submit a paper copy of cited US Published Applications

init	Cite.No.	Pub. No.	Date	Applicant	Kind	Class	Subclass
*	1	20030073348	2003-04-17	Ries et al.	A1	439	578
100	2	20030050549	2003-03-13	Sochor	A1	600	378

Signature

Examiner Name	Date
alysa ato	5-80-05

ELECTRONIC INFORMATION DISCLOSURE STATEMENT

Electronic Version v18 Stylesheet Version v18.0

> Title of Invention

Multi-Polar Electrical Medical Lead Connector System

Application Number:

10/646545

Confirmation Number:

9714

First Named Applicant:

Douglas Hine

Attorney Docket Number: P-11138.00

Art Unit:

3731

Search string:

(6295475 or 5766042 or 5423873 or 5070605 or 4182345 or 4142532 or 4583543 or 5060649 or 6044302 or 5328442 or 4628934 or 5000177 or 5050602 or 5007864 or 20020115343).pn.

US Patent Documents

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Cite.No.	Patent No.	Date	Patentee	Kind	Class	Subclass
W	1	6295475	2001-09-25	Morgan	B1	607	122
Ш	2	5766042	1998-06-16	Ries et al.	Α	439	668
Ш	3	5423873	1995-06-13	Neubauer et al.	Α	607	68
Ш	4	5070605	1991-12-10	Daglow et al.		29	842
	5	4182345	1980-01-08	Grose		128	419 P
Ш	6	4142532	1979-03-06	Ware		128	419 P
Ш	7	4583543	1986-04-22	Peers-Trevarton		128	419 P
Ш	8	5060649	1991-10-29	Hocherl et al.		128	419 P
Ш	9	6044302	2000-03-28	Persuitti et al.	Α	607	37
	10	5328442	1994-07-12	Levine	A	600	17
Ш	. 11	4628934	1986-12-16	Pohndorf et al.		128	419 PG
	12	5000177	1991-03-19	Hoffmann et al.		128	419 P
Ш	· 13	5050602	1991-09-24	Osypka ·		128	419 P
Ш	14	5007864	1991-04-16	Stutz, Jr.		439	651

US Published Applications



Applicant is not required to submit a paper copy of cited US Published Applications

init	Cite.No.	Pub. No.	Date	Applicant	Kind	Class	Subclass
M	1	20020115343	2002-08-22	Sommer et al.	A1	439	578

Signature

Examiner Name	Date
alym atter	5-29-05

Notice of References Cited Application/Control No. 10/646,545 Examiner Alyssa M. Alter Applicant(s)/Patent Under Reexamination HINE ET AL. Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	Α	US-4,628,934	12-1986	Pohndorf et al.	607/27
	В	US-4,469,104	09-1984	Peers-Trevarton, Charles A.	607/37
	С	US-5,843,141	12-1998	Bischoff et al.	607/37
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	К	US-			
	L	US-			
	М	US-			

FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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